

ORDER no. 1345/2016 of 24 November 2016
on daily reporting of stocks and trade operations carried out with medicinal products for human use included in the National Catalogue of Prices for medicinal products authorised for marketing in Romania by medicinal product wholesalers, importers, authorised manufacturers and closed- and open-circuit pharmacies

ISSUING BODY: The MINISTRY OF HEALTH

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On seeing the Approval Report No. V.V.V. 6 447 of 24 November 2016 of the Directorate for Policies on Medicinal Products and Medical Devices of the Ministry of Health,

Taking into account provisions of Article no. 7 i) and of Article no. 804 (2) of Law no. 95/2006 on healthcare reform republished as amended,

Pursuant to Article 7 (4) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as amended,

the **Minister of Health** hereby issues the following order:

Article 1

(1) As of the date of this order entry into force, wholesalers of medicinal products for human use, importers and authorised manufacturers shall submit daily reports to the Ministry of Health on the status of their stocks and trade operations, distribution outside Romania included, conducted with medicinal products for human use in their portfolio, price-approved as per the National Catalogue of Prices for medicinal products authorised for marketing in Romania, hereinafter referred to as the CaNaMed.

(2) As from the date of entry into force of this order, closed- and open circuit pharmacies are required to report daily to the Ministry of Health on the status of stocks and trade operations carried out with human medicinal products price-approved as per the CaNaMed.

(3) Submission of information specified in (1) and (2) shall be carried out using the electronic reporting system developed for the Ministry of Health by the Service for Special Telecommunications and hereinafter referred to as the Electronic Reporting System, whose functions are described in Annex 2, which is integral part of this order.

Article 2

Communication to the Ministry of Health of the status of supplies and trade operations via the Electronic Reporting System shall be carried out as follows:

a) For each medicinal product price-approved as per the CaNaMed, medicinal product wholesalers, importers and authorised manufacturers and closed- and open circuit pharmacies shall report the following: medicinal product identification code (CIM), amount entered since the latest report, amount exited since the latest report, stocks on current reporting date, type of beneficiary (natural or legal entity), beneficiary country;

b) amount and inventory shall be given in therapeutical units.

Article 3

According to Law No. 11/1991 on competition, as amended, information regarding individual stocks of open circuit pharmacies is a trade secret.

Article 4

(1) Provisions of Articles 1-3 shall enter into force 90 days from publication date.

(2) The Electronic Reporting System developed for the Ministry of health by the Service for Special Telecommunications shall be operational within 30 days from publication of this order.

(3) No later than 180 days as of publication of this order, a software solution shall be developed in the Electronic Reporting System for record and track of complaints submitted by pharmacies with respect to medicinal product shortages. Technical specifications of the software solution are published on the Ministry of Health website under the "News" section, within 90 days from publication of this order.

Article 5

This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health

Vlad Vasile Voiculescu

Bucharest, 24 November 2016.

Nr. 1345.

FUNCTIONS of the Electronic Reporting System

Article 1

(1) The Electronic Reporting System is a software platform developed for the Ministry of Health by the Service for Special Telecommunications.

(2) The main purpose of the Electronic Reporting System is to provide the Ministry of Health with a nationwide overview of stocks of medicinal products included in the CaNaMed, aiming to contribute to development of an integrated information system for public health management.

Article 2

(1) Functions of the Electronic Reporting System are as follows:

a) to enable secured access by both the Ministry of Health and the NAMMD via the Ministry of Health website to information on the nation- and region- wide status of stocks for each medicinal product (INN and CIM), as established by Law No. 315/2004 on regional development in Romania, as amended, as well as at county level, pharmacy level excluded;

b) to enable public access via the Ministry of Health website to information on the nation- and region-wide status of stocks for the medicinal product category with the same INN, pharmaceutical form and strength, as established by Law no. 315/2004 as amended, pharmacy level excluded;

c) to enable track of parallel exports.

(2) By way of Electronic Reporting System design and configuration, the Ministry of Health or NAMMD access is solely allowed to information specified in (1), precluding their access to information on medicinal product at specific pharmacy level or the raw data database.

Article 3

(1) Daily reporting is encrypted via a web service whose technical specifications are defined by the Service for Special Telecommunications, in collaboration with the Ministry of Health, and published on the Ministry of Health website under the "News" section.

(2) Information shall be communicated from 8.00 hr to 20.00 hr daily, for the previous day. In case of several reports submitted from one site for the same day, the latest report shall be taken into account.

(3) Authentication into the system and ensuring authenticity and protection of the identity of reporting entities is achieved through use of qualified digital certificates. Closed- and open circuit pharmacies shall use digital certificates enrolled in the Unique Integrated Information System (SIUI). Medicinal product wholesalers, importers and authorised manufacturers shall enlist qualified digital certificates into the system using an application made available on the Ministry of Health website.

(4) Expired medicinal products are out of the scope of stock reporting pursuant to (1).

(5) In case of exceptional and unanticipated technical difficulties, reporting may be delayed for no longer than 72 hours. Reporting is not required for the days when entities with reporting obligations are outside operation schedule.

Article 4

By way of exception from provisions of Article 2 (2) and of Article 3 (3) of this Annex:

a) On approval by the Minister of Health, specialised NAMMD units may acquire information on individual pharmacy stocks by means of their control actions;

(b) On approval by the Minister of Health, specialised NAMMD units may be provided with a list of all entities in possession of stocks of a particular medicinal product in cases of that medicine withdrawal requested on NAMMD behalf or by the European Medicines Agency.